SUPPLEMENTARY INFORMATION
CERTIFICATE TO FOREIGN GOVERNMENT REQUESTS

1. Requester information (name; firm; address; telephone number; FAX number; firm Tax ID code):

2. Manufacturer information (firm; address (P.O. Box not acceptable); registration number; license number, if applicable; date of last FDA inspection)

3. Product information should include the following:
   Trade Name, Proper Name
   Marketing status (PLA, 510k, PMA, or NDA). Include number and date approved.

4. Was the product ever recalled? If "Yes", state the recall number and close out date.

5. List country(ies) for which the Certificates are requested.

6. Indicate what product information should appear on the certificate, if the country destination should be listed on the certificate, and the total number of certificates requested.

7. If the product(s) being exported is human tissue intended for transplantation, please ensure that the Exporter's Certification Statement, "Certificate to Foreign Government" (For Human Tissue Intended for Transplantation), is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

EXPORTER'S CERTIFICATION STATEMENT - "Certificate to Foreign Government"

Firm Name:

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that the company, the manufacturing plant, and the product(s) being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act.

_____

Signature Date

_____

Name and Title

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to $250,000 in fines and up to 5 years imprisonment.

EXPORTER'S CERTIFICATION STATEMENT - "Certificate to Foreign Government" (For Human Tissue Intended for Transplantation)

Firm Name:

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that the company, the manufacturing plant, and the product(s) being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1270, Human Tissue Intended for Transplantation.

_____

Signature Date

_____

Name and Title

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to $250,000 in fines and up to 5 years imprisonment.